- (i) Is subject to full review by CMS or a CMS agent, in accordance with this part; and
- (ii) May be subject to suspension, revocation, or limitation of its certificate of accreditation under this part.
- (2) A laboratory with a certificate of accreditation is again deemed to meet the condition-level requirements by virtue of its accreditation when the following conditions exist:
- (i) The laboratory withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation inspection, PT results, or notification of any adverse actions resulting from PT failure.
- (ii) The laboratory withdraws any prior refusal to allow a validation inspection.
- (iii) CMS finds that the laboratory meets all the condition-level requirements.
- (b) CLIA-exempt laboratory. If a CLIA-exempt laboratory fails to comply with the requirements specified in §493.565, CMS notifies the State of the laboratory's failure to meet the requirements.

§ 493.569 Consequences of a finding of noncompliance as a result of a validation inspection.

- (a) Laboratory with a certificate of accreditation. If a validation inspection results in a finding that the accredited laboratory is out of compliance with one or more condition-level requirements, the laboratory is subject to—
- (1) The same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following an inspection under this part; and
- (2) Full review by CMS, in accordance with this part; that is, the laboratory is subject to the principal and alternative sanctions in §493.1806.
- (b) CLIA-exempt laboratory. If a validation inspection results in a finding that a CLIA-exempt laboratory is out of compliance with one or more condition-level requirements, CMS directs the State to take appropriate enforcement action.

§ 493.571 Disclosure of accreditation, State and CMS validation inspection results.

- (a) Accreditation organization inspection results. CMS may disclose accreditation organization inspection results to the public only if the results are related to an enforcement action taken by the Secretary.
- (b) State inspection results. Disclosure of State inspection results is the responsibility of the approved State licensure program, in accordance with State law.
- (c) CMS validation inspection results. CMS may disclose the results of all validation inspections conducted by CMS or its agent.

§ 493.573 Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs.

- (a) Comparability review. In addition to the initial review for determining equivalency of specified organization or State requirements to the comparable condition-level requirements, CMS reviews the equivalency of requirements in the following cases:
- (1) When CMS promulgates new condition-level requirements.
- (2) When CMS identifies an accreditation organization or a State licensure program whose requirements are no longer equal to, or more stringent than, condition-level requirements.
- (3) When an accreditation organization or State licensure program adopts new requirements.
- (4) When an accreditation organization or State licensure program adopts changes to its inspection process, as required by §493.575(b)(1), as applicable.
- (5) Every 6 years, or sooner if CMS determines an earlier review is required.
- (b) Validation review. Following the end of a validation review period, CMS evaluates the validation inspection results for each approved accreditation organization and State licensure program.
- (c) Reapplication procedures. (1) Every 6 years, or sooner, as determined by CMS, an approved accreditation organization must reapply for continued approval of deeming authority and a State licensure program must reapply